Exhibit 12

U.S. FOOD & DRUG ADMINISTRATION

60 8th Street, N.E.
Atlanta, Georgia 30309
404.253.1161 Office
404.253.1202 Fax
Atlanta District

04/10/2018

Mr. Chen Baohua, President
Zhejiang Huahai Pharmaceutical Co., Ltd.
Gucheng Street
Linhai, 317024
Zhejiang, China

Reference: Inspection Date(s): 01/22/2018 - 01/26/2018

Location: Zhejiang Huahai Pharmaceutical Co., Ltd.
Xunqiao Xinjie
Linhai
Taizhou, 317024, CN

Dear Mr. Baohua:

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at 404-669-4440.

For more information on the U.S. FDA, please visit our website at www.fda.gov.

Sincerely,

Digitally signed by Vincent M. Williams -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300092435, cn=Vincent M. Williams -S
Date: 2018.04.10 13:34:24 -04'00'

FEI: 3003999190
Enclosure: Establishment Inspection Report (EIR)

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SUMMARY (RAG)

This Pre-Approval Inspection (PAI) of a manufacturer of Human drugs was conducted per FACTS Assignment # 11778309 and eNSpect Operation ID# 79787. The inspection was conducted in accordance with Compliance Program Guidance Manual (CPGM) 7346.832, *Pre-approval Inspections/Investigations* and CPGM 7356.002, *Drug Manufacturing Inspection.* The previous inspection was a PAI only inspection conducted June 5-14, 2017 and was classified No Action Indicated (NAI).

The inspection revealed that Zhejiang Huahai Pharmaceutical Co., Ltd, referred to as "the firm" or "Huahai", throughout this report, operates as a manufacturer of Over-the-Counter (OTC) and prescription (R_x) drug products. The current inspection was a product specific PAI for ANDA 210771, Levomilnacipran Hydrochloride Extended-Release (ER) Capsules under profile CTR = Capsules, modified (extended or delayed release forms). This preannounced PAI was initiated in response to the request from the Center for Drug Evaluation and Research (CDER). The systems covered during the inspection were Quality, Production, Materials, Facilities and Equipment, Laboratory Controls, and Packaging and Labeling.

Inspectional coverage was based on CPGM 7346.832 as provided by CDER. The documents reviewed included, but were not limited to: analytical test records, batch records, deviation/corrective action reports, change controls, Out-of-Specification (OOS) investigations, validations, technology transfers, stability monitoring, rejects, and training records.

No Form FDA-483, Inspectional Observations was issued at the close of this inspection on 27 January 2018.

No samples were collected and no refusals were encountered during the inspection.

ADMINISTRATIVE DATA (RAG)

Inspected firm:	Zhejiang Huahai Pharmaceutical Co., Ltd
Location:	Xunquiao, Linhai, 317024 Zhejiang, China
Phone:	+86 (576) 8501 6001
FAX:	
Mailing address:	Xunquiao, Linhai, 317024 Zhejiang, China
Dates of inspection:	01/22/2018, 01/23/2018, 01/24/2018, 01/25/2017, 01/26/2018
Days in the facility:	5
Participants:	Reba A. Gates, Lead Investigator Kara D. Dobbin, Investigator

The inspection of this facility was a team inspection conducted by Lead Investigator, Reba A. Gates (RAG), and Investigator, Kara D. Dobbin. This report was written by the team. The team member(s) that completed the sections of this report are identified by the initials to the right of the section title. At the initiation of the inspection on 22 January 2018, the team presented credentials to Mr. Chen Baohua, President, Mr. Jun Du, Executive Vice President, and Mr. Jenson (Cunxiao) Ye, Vice President Qualified Person Licensed Pharmacist. Mr. Chen identified himself as the most responsible person at the site.

Huahai Pharmaceuticals employs approximately 6000 employees globally. The production and quality unit hours of operation are 8:00 AM to 5:00 PM, Monday through Saturday. Depending on the workload, a second shift may be added.

All correspondence should be sent to:

Chen Baohua, President
Gucheng Street,
Linhai, 317024
Zhejiang, China
Email: chen@huahaipharm.com

INTERSTATE COMMERCE/JURISDICTION (RAG)

FDA regulated activities performed at Zhejiang Huahai Pharmaceutical Co., Ltd. include the manufacture, packaging, and shipment of human drug substances in the form of finished dosage formulations and APIs. The firm is registered with US FDA as a finished dosage drug manufacturer. The drug products manufactured at this facility are intended for the treatment of disease in humans and as such, the firm is subject to the adulteration provisions as defined by the Food, Drug and Cosmetic Act, which requires all drugs to be manufactured in conformance with current Good Manufacturing Practices (cGMP).

The firm distributes manufactured drug products for domestic and international markets. The products intended for the international markets are exported to different distribution centers located in the U.S. and Europe.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED (RAG)

On 22 January 2018, we arrived at the firm with Mr. Jie Wang, Vice President, Business Development, from the firm's Shanghai location. Upon arrival we were escorted to the executive conference room by Mr. Jenson (Cunxiao) Ye, Vice President Qualified Person and Licensed Pharmacist. We presented our credentials to Mr. Chen Baohua, President; Mr. Jun Du, Executive Vice President; and Mr. Jenson (Cunxiao) Ye, Vice President Qualified Person Licensed Pharmacist. Mr. Chen identified himself as the most responsible person at the site. A corporate presentation was given by Jie Wang.

The following are the names and titles of management personnel who were present at various points during the inspection. These individuals provided information or directed appropriate personnel to provide information as requested: